Attachment 4 – 510(k) Summary

APR 2 5 2013

510K Summary

Date:	March 13, 2013
Submitter:	Zavation LLC 501 Avalon Way Brandon, MS 39047 Phone: 601-919-1119 Fax: 800-447-1302
Contact person:	John Walker
Type of 510(k) submission:	Traditional
Trade name:	Zavation Cervical Plate System
Common name:	Anterior Cervical Plate
Classification regulation:	888.3060
Device classification:	Class II
Classification Panel:	Orthopedic
Product code:	KWQ
Basis for submission:	Addition of optional screws and plates

Device Description:
The Zavation Cervical Plate System consists of self-tapping/self-drilling screws and plates. Screws are available in a variety of diameter and length combinations. Plates are available in a variety of lengths.

Intended Use:
The Zavation Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

Materials:
The Zavation Cervical Plate System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Predicate Device:
ALINE, Smith & Nephew (K943523)
CSLP, Synthes (K945700)
Vectra-one, Synthes (K071667)
Uniplate, Depuy Spine (K042544)
Zavation Cervical Plate (K112533)

Technological Characteristics:
The Zavation Cervical Plate System possesses the same technological characteristics as the predicate. These include: basic design (plate designed fixation system having various screw diameters and lengths), material (titanium alloy), sizes (variety of plate and screw sizes), and intended use (as described above).

Performance Data:
Static compression bending and torsion, and dynamic compression bending were performed according to ASTM F1717 on a worst-case, cervical plate construct. The mechanical test results demonstrated that the Zavation Cervical Plate System performs as well as or better than the predicate devices.

Conclusion:
The Zavation Cervical Plate System is substantially equivalent to the device referenced above and is therefore safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Zavation, LLC
% Mr. John Walker
Engineering Manager
501 Avalon Way
Brandon, Mississippi 39047

Letter dated: April 25, 2013

Re: K130030
Trade/Device Name: Zavation Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 13, 2013
Received: March 18, 2013

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3 – Indications for Use Statement

Indications for Use

510(k) Number (if known): K130030

Device Name: Zavation Cervical Plate System

Indications For Use:

The Zavation Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices